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CALIFORNIA STEM CELL TREATMENT CENTER, INC., CELL SURGICAL NETWORK CORPORATION, ELLIOT B. LANDER, M.D. and MARK BERMAN, M.D.

UNITED STATES DISTRICT COURT

CENTRAL DISTRICT OF CALIFORNIA

EASTERN DIVISION

UNITED STATES OF AMERICA,

Plaintiff,

v.

CALIFORNIA STEM CELL TREATMENT CENTER, INC., a California corporation, CELL SURGICAL NETWORK CORPORATION, a California corporation, and ELLIOT B. LANDER, M.D., MARK BERMAN, M.D., individuals,

Defendants.

CASE NO. 5:18-CV-01005-JGB-KK

Hon. Jesus G. Bernal
Riverside, Courtroom 1

DEFENDANTS' TRIAL BRIEF

Action Filed: May 9, 2018
Trial Date: May 4, 2021

I. INTRODUCTION

This case is a textbook example of federal governmental overreach, whereby the FDA seeks to interfere with, and dramatically limit, a patient's relationship with her physician and what she can do with her own body. The case turns on two incontrovertible principles: (1) a human cell is not a drug, and (2) a surgical procedure is not the manufacture of a drug. The SVF Surgical Procedure is a groundbreaking technique that utilizes chemical cutting to isolate human cells, which are subsequently relocated to other parts of a person's body. This procedure does not create anything new; rather, the surgical procedure simply isolates an individual's pre-existing cells for use within the same individual's body. Dr. Berman and Dr. Lander, as licensed physicians, may utilize any drug, medical device, or surgical procedure that they determine is in the best course of treatment for their patients, with informed consent from the patient. Here, Dr. Berman and Dr. Lander used their combined seventy-eight years of medical and surgical training to design a bespoke, safe treatment for their patients that uses each patient's individual cells. Numerous federal courts and the FDA's own regulations confirm that the federal government cannot regulate Dr. Berman's or Dr. Lander's practice of medicine. The government's continued pursuit of this case cuts against well-settled regulatory law and the Constitution.

In addition to exceeding its permissible regulatory authority, the government's theory rests of faulty statutory interpretations and factual predicates. First, the 2017 Guidance Document is not subject to any deference and cannot supplant an unambiguous regulation, namely 21 C.F.R. 1271.15(b). Second, and alternatively, the 2017 Guidance Document is not a valid modification of existing regulations because the Government did not comply with Constitutional and federal laws that require a notice and comment period and appropriate signatory before enacting any substantive change to regulations. Third, there is no interstate commerce because the patients retain ownership of their cells at all times. Fourth,

the Government lacks standing to pursue any claim related to the SVF/ACAM2000 Surgical Procedure because the ACAM2000 was seized before this case was even filed. Judgment should be entered in favor of Dr. Berman and Dr. Lander, as well as Cell Surgical Network and California Stem Cell Treatment Center, because the activity at issue is the lawful practice of medicine, not the manufacture of any drug.

II. ARGUMENT

A. The FDA Has No Jurisdiction Over The Practice Of Medicine

Physicians can use FDA-cleared medical devices and FDA-approved pharmaceuticals in the manner best suited for the care and treatment of their patients, with informed consent. Congress has explicitly rejected "any intent to directly regulate the practice of medicine." *See Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 351 ¶ n.5 (2001) (citing Beck & Azari, FDA, Off–Label Use, and Informed Consent: Debunking Myths and Misconceptions, 53 Food & Drug L.J. 71, 72 (1998) (stating that "[o]ff-label use is widespread in the medical community and often is essential to giving patients optimal medical care, both of which medical ethics, FDA, and most courts recognize")); *U.S. ex rel. Modglin v. DJO Glob. Inc.*, 114 F. Supp. 3d 993, 999 (C.D. Cal. 2015), *aff'd sub nom. United States v. DJO Glob., Inc.*, 678 F. App'x 594 (9th Cir. 2017). SVF cells are not a drug, and even if they were, existing statute, 21 U.S.C. § 360 excludes defendants from requirements to register with the FDA. The statute specifically exempts:

- Practitioners licensed by law to prescribe or administer drugs or devices and who manufacture, prepare, propagate, compound, or process drugs or devices solely for use in the course of their professional practice [and]
- Persons who manufacture, prepare, propagate, compound, or process drugs or devices solely for use in research, teaching, or chemical analysis and not for sale.

Each step of the SVF Surgical Procedure, Expanded MSC Surgical Procedure, and SVF/ACAM2000 Surgical Procedure uses FDA-cleared and/or approved medical devices and pharmaceuticals as part of the surgical procedure. Defendants are practicing medicine, not manufacturing pharmaceuticals.

The recognition that the FDA does not have jurisdiction over the practice of medicine is consistent with the limitations set by the Commerce Clause. First, the SVF cells are never sold—the patient has exclusive control and ownership of their own cells at all times. The SVF cells, Expanded MSC cells, and SVF/ACAM2000 are not a fungible good. *See* 21 U.S.C. § 331(k) ("any . . . act with respect to a food, drug, device, tobacco product, or cosmetic, if such act is done while such article is held ***for sale*** (whether or not the first sale) ***after shipment in interstate commerce*** . . ." (emphasis added)). Second, the SVF cells and SVF/ACAM2000 cells do not cross state lines. Third, the FDA's expansive position that interstate commerce exists because fluids used in the surgical procedures cross state lines would make every surgical procedure interstate commerce, which is contrary to the universal recognition that the practice of medicine is exclusively regulated by state governments.

The FDA regulations do not apply to the SVF Surgical Procedure, Expanded MSC Surgical Procedure, or SVF/ACAM2000 Surgical Procedure because each procedure constitutes the practice of medicine and does not constitute interstate commerce.

B. <u>The Same Surgical Procedure Exception Applies</u>

The SVF Surgical Procedure plainly falls within the Same Surgical Procedure Exception ("SSP Exception"), 21 C.F.R. § 1271.15: the procedure involves Human Cells, Tissues, or Cellular or Tissue-Based Products ("HCT/Ps"), is autologous, is completed during a single procedure, and implants the same cells that were removed from a single patient. The SVF Surgical Procedure is not a drug under the unambiguous regulation.

The modern practice of medicine has developed to where surgeons can chemically cut, i.e., isolate, human cells from within human tissue. This is no different from surgical procedures using mechanical cutting, including the following examples, some of which are taken directly from the FDA's Guidance regarding the SSP Exception:

a. **Coronary artery bypass surgery:** A surgeon will remove a healthy blood vessel from a patient's leg, arm, or chest, along with blood. Next, the surgeon will cut the blood vessel to the correct size and attach the ends of the vessel above and below the diseased artery so that blood flow is redirected around the diseased artery.

b. **Fascial graft reconstructive surgery:** A surgeon removes a piece of muscle and its overlying fascia. Then, the surgeon sizes and strips the fascia from the muscle to fit the target site, removing unnecessary portions of muscle. The muscle no longer can repair, replace or reconstruct, however, the fascia retains its inherent biological characteristics and can be used as a suitable substitute for a tendon graft.

c. **Brain surgery involving dural repair using autologous fat:** As part of surgery to remove basicranial and convexity extraaxial tumors, the surgeon first removes abdominal adipose, then crushes the adipose into a thin layer, and finally places the graft to reconstruct dural defects, thereby preventing cerebrospinal fluid leaks, infections, hypertensive pneumocephalus, and other common complications.

d. **Skin grafting:** A surgeon removes a piece of skin from the patient. With the skin, additional tissue and blood is removed. Then, the surgeon cleans and sizes the tissue, and may create a mesh within the tissue to facilitate shaping and sizing to the target area.

e. Parathyroidectomy: A surgeon removes the parathyroid glands. Next, the surgeon cuts the parathyroid to size for reimplantation. Note, the FDA permits this procedure to occur over multiple days.

As the FDA recognizes in the above procedures, the relevant HCT/Ps are the ***target HCT/Ps,*** not the additional material that is concurrently removed. The SVF Surgical Procedure is not materially different from the procedures expressly permitted by the FDA. First, a surgeon removes the targeted HCT/Ps—the SVF that includes stem cells—from the patient. Along with the SVF and stem cells, larger cells, such as adipocytes, are also removed from the patient. Next, the surgeon cleans and sizes (filters) the SVF to isolate the stem cells and implants those stem cells that were removed back into the same patient. Accordingly, the SVF Surgical Procedure expressly falls within the SSP Exception because it implants into the same patient cells that were removed from that patient.

In an effort to overcome the clear bar to their suit, the government attempts to create ambiguity where none exists under the guise of interpretation in the 2017 Guidance. *See Kisor v. Wilkie*, 139 S. Ct. 2400, 2414 (2019) ("[T]he possibility of deference can arise only if a regulation is genuinely ambiguous."); *see also Christensen v. Harris County*, 529 U.S. 576, 588 (2000) ("The regulation in this case, however, is not ambiguous . . . . To defer to the agency's position would be to permit the agency, under the guise of interpreting a regulation, to create *de facto* a new regulation."). The Supreme Court has repeatedly rebuked such substantive changes disguised as "interpretation." *See Azar v. Allina Health Serv.*, 139 S. Ct. 1804, 1810-11 (2019) (requiring substantive regulatory changes to comply with notice and comment requirements, obligation to meet with stakeholders).

First, the 2017 Guidance is not subject to deference because the underlying regulation, 21 C.F.R. § 1271.15, is unambiguous, and the FDA's interpretation is unreasonable and an unfair surprise. *See Kisor*, 139 S. Ct. 2400. Second, the 2017 Guidance cannot be a valid modification of the existing regulation because it was

not subject to a proper notice and comment period. *See Azar*, 139 S. Ct. 1804. The government attempts to narrow the SSP Exception by arguing that the cells must be in their "original" form or be "minimally manipulated." Neither requirement is stated in the SSP Exception.

The SSP Exception unambiguously states that a tissue ***or human cell*** is not a drug requiring FDA regulation if it is removed from an individual and then implanted in the same individual. The FDA has not lawfully modified this law and the SSP Exception applies to the SVF Surgical Procedure.

C. The FDA Does Not Have Standing For Injunctive Relief

The FDA does not have standing for injunctive relief for the SVF/ACAM2000 Surgical Procedure because the government already seized the ACAM2000 and maintains exclusive control over its distribution. It is well-settled that Defendants' prior surgical procedures "do[] not in [themselves] show a present case or controversy regarding injunctive relief . . . ." *See Lujan v. Defenders of Wildlife*, 504 US 555, 564 (1992). The government has the burden of demonstrating standing and they fail to do so.

Defendants stopped performing the SVF/ACAM2000 Procedure well before the initiation of this lawsuit. The government seized the ACAM2000 vials that Defendants used for the clinical study from Defendants' research sponsor, StemImmune. The government has exclusive control over ACAM2000, so given the seizure and lack of access to ACAM2000, Defendants cannot perform this procedure at this time, or anytime going forward, unless the government reverses its position and permits them to do so. There is no real or immediate threat of alleged repeated injury. Further, Defendants used ACAM2000 for clinical research at no charge to their patients in compliance with 21 U.S.C. § 360.

III. CONCLUSION

The federal government has overreached its Constitutional, Congressional, and regulatory authority by pursuing this case. This case is an attempt to interfere

with the practice of medicine in violation of the Commerce Clause and without complying with any federal administrative laws. Chemical cutting and the autologous implantation of a patient's own human cells is not a drug; it is a surgical procedure that is part of the practice of medicine. Accordingly, judgment should be entered in favor of Defendants.

Dated: April 27, 2021

JONES DAY

By: */s/ Celeste M. Brecht*
Celeste M. Brecht

Attorneys for Defendants CALIFORNIA STEM CELL TREATMENT CENTER, INC., CELL SURGICAL NETWORK CORPORATION, ELLIOT B. LANDER, M.D. and MARK BERMAN, M.D.